

Appl. No. 10/671,348
Amendment dated: June 21, 2006
Reply to OA of: March 21, 2006

REMARKS

This is in response to the Official Action of March 21, 2006 in connection with the above-identified application. Applicants have amended the claims of the instant application in order to more precisely define the scope of the present invention, taking into consideration the outstanding Official Action.

Specifically, Applicants have amended claim 1 to incorporate the subject matter of claim 2. Claim 1 now recites the additional steps of f) opening the pocket and g) separating the resulting opened pocket from the hardened cement. In light of this amendment, claim 2 has been canceled and claims 3, 7 and 8 have been amended to depend from claim 1 instead of now-canceled claim 2.

In light of the amendment to the claims, Applicants respectfully submit that all claims now pending in the instant application are in full compliance with the requirements of 35 U.S.C. §112 and are clearly patentable over the references of record.

Applicants begin by noting with appreciation the indication in the outstanding Official Action that subject matter recited in claims 7 and 9-13 would be allowable if rewritten in independent format including all of the limitations of the base claim and any intervening claims. However, Applicants believe that amended claim 1 is patentable over the references of record and therefore respectfully decline at this time to incorporate any of the indicated allowable subject matter into claim 1.

The provisional non-statutory obviousness-type double patenting rejection of claims 1, 3, 5, 9, 10, 12 and 13 over claims 1, 2, 5, 6, 10-12, 14 and 15 of co-pending Application Serial No. 10/393,044 has been carefully considered but is most respectfully traversed in light of the following comments.

The Official Action urges that while the conflicting claims are not identical, they are not patentably distinct from each other because the independent claims of each patent application claim a method including preparing a cement paste, disposing a pocket or balloon, injecting paste into the pocket or balloon, applying a pressure to the paste and allowing the paste to harden. However, this generalization of the claims

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ignores important features of the presently claimed invention that are neither claimed in the co-pending application nor obvious in light of the co-pending application, thereby making the claims of the two applications patentably distinct.

Specifically, the present invention is drawn to a method wherein a pocket that is made from a material penetrable to the liquid component but not to the solid component of the cement paste is disposed in a bone cavity. Further, the present claims are drawn to a method whereby the cement paste is injected into the pocket, and then once the cement has filled the pocket, further pressure is exerted to force some of the liquid component out of the pocket through the pocket material that is penetrable to the liquid component. To the contrary, the claims of the co-pending application do not recite these features, and in fact, recite a balloon that is filled with cement paste wherein no cement paste leaks through the balloon and no additional pressure is exerted after the cement paste has filled the balloon. In light of these differences, the claims of each invention are clearly patentably distinct from each other, and the difference between the two sets of claims is not an obvious modification of one or the other. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Regardless of whether the two co-pending applications are patentably distinct from each other, Applicants note that the rejection set forth in the Official Action is a provisional rejection, since no claims from either patent have yet to mature into a patent. In light of this provisional rejection, Applicants respectfully request that the rejection be held in abeyance until one application matures to a patent.

The rejection of claim 1 under 35 U.S.C. §102(e) as being anticipated by Osario et al. (US Pat. No. 6,726,691) has been carefully considered but is most respectfully traversed in light of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2

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USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

The Official Action urges that Osario discloses a method including preparing a cement paste, disposing a pocket, and injecting the cement paste into the balloon through a hollow tube by applying pressure. Applicants specifically traverse these statements and respectfully submit that Osario fails well short of disclosing every element of the claimed invention.

Firstly, with respect to the assertion that cement paste is injected into a balloon through a hollow tube, Applicants note that the invention disclosed in Osario is for creating a cavity in the bone before injecting cement paste into the bone. This is clearly set forth in, for example, the Abstract and the Summary of the Invention. The Summary of the Invention states at col. 3, lines 62-68 that a cavity forming device (i.e., a balloon as disclosed at col. 4, lines 41-42), is inserted through a needle into a vertebral body. The cavity forming device compresses cancellous bone in the vicinity of the distal tip of the needle by filling the balloon with an "inflation medium", thereby forming a cavity within the bone. The cavity forming device and inflation medium are then removed and cement is introduced directly into the cavity through a spinal needle.

Thus, a careful reading of Osario reveals that cement paste is not filled in the balloon as urged in the Official Action, but rather is filled in the space formed by the balloon after the balloon is removed. Accordingly, it is abundantly evident that Osario does not disclose injecting a cement paste into a pocket as claimed in the instant application. Because Osario fails to disclose every element of the claims, the reference cannot properly support a §102 rejection according to the guidelines set forth in MPEP §2131 and should therefore be withdrawn.

Because the invention described in Osario is directed to forming a cavity in the

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bone by using a balloon catheter, it necessarily follows that the inflation medium used to cause the balloon to expand and thereby create the cavity cannot be a cement paste. This is further supported in the specification, wherein it is stated at col. 8, lines 46-49 that the inflation medium may be air, nitrogen, saline or water. Filling the cavity forming balloon with a cement paste would prevent the invention from accomplishing its intended purpose of forming a cavity, since the cement paste would harden and permanently fill the space created.

Applicants also specifically traverse the statement in the Official Action that the balloon material (i.e., the cavity forming device) would inherently have pores capable of transmitting liquid. There is absolutely no disclosure in Osario that would suggest that any material suitable for use as the balloon portion of the cavity forming device would be porous and capable of transmitting liquid. Some of the suggested materials for use as the balloon include metal, plastics, composite materials, polyethylene, Mylar, rubber and polyurethane, none of which would be porous to the point of allowing liquid to pass through the material (see, e.g., col. 12, lines 10-15). Further, using a material that is porous to liquid for the balloon of the cavity forming device would prevent the invention from accomplishing its intended purpose. That is to say, if the balloon portion of the cavity forming device were porous to liquid, then insertion of liquid or inflation medium into the balloon would not cause the balloon to inflate and create a cavity. The liquid would escape from the balloon and therefore the balloon would never expand to a size that creates a cavity in the bone.

Accordingly, absent more concrete support in the disclosure suggesting to the contrary, Applicants respectfully submit that Osario fails to disclose a pocket made from a material penetrable to liquid but impenetrable to powder of the cement paste as claimed in the instant application. As Osario fails to disclose every element of the claimed invention, it is respectfully submitted that the reference is incapable of properly supporting a §102 rejection according to the guidelines set forth in MPEP §2131 and should therefore be withdrawn.

Finally, Applicants feel it should be emphasized that presently amended claim

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1 requires two steps of applying pressure. The first step of applying pressure is recited in step c), wherein the cement paste is injected into the pocket. Then, a second step of applying pressure as recited in step d) is performed. This second step is performed after all of the cement paste has been injected into the pocket, and is what causes the liquid to transfer through and out of the material of the pocket to increase the powder to liquid ratio. This method allows for ease of injection of the cement paste into the pocket due to the better viscosity associated with a cement paste having a lower powder to liquid ratio, while also taking advantage of the quicker hardening of the cement paste associated with a higher powder to liquid ratio. Two powder to liquid ratios and their associated characteristics are taken advantage of in the presently claimed invention.

The Osario reference fails to disclose this feature of the presently claimed invention. There is absolutely no mention in Osario of the balloon material being porous to liquid but not to solid, and there is absolutely no mention of first filling the cavity forming device with fluid and then asserting more pressure to force liquid out of the balloon. Accordingly, as Osario clearly fails to disclose these features of the presently claimed invention, it is respectfully submitted that the reference is incapable of properly supporting a §102 rejection according to the guidelines set forth in MPEP §2131. Applicants therefore request that this rejection be withdrawn.

The rejection of claims 2-6, 8, 14 and 15 under 35 U.S.C. §103(a) as being unpatentable over Osario in view of Hochschuler et al. (US Pub. No. 2002/0058947), the rejection of claim 16 under 35 U.S.C. §103(a) as being unpatentable over Osario in view of Hochschuler as applied to claim 14 and further in view of Daniel et al. (US Pub. No. 2002/0133148) and the rejection of claim 17 under 35 U.S.C. §103(a) as being unpatentable over Osario in view of Liu et al. (US Pat. No. 6,726,691) have each been carefully considered but are most respectfully traversed in light of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner's attention to the basic requirements of a *prima facie* case of obviousness as set forth in the MPEP § 2143. This section states

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that to establish a *prima facie* case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also note MPEP §2143.01, which states in part that, if a proposed modification would render the prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence presented by applicant and the citation of *In re Soni* for error in not considering evidence presented in the specification.

Claims 2-6, 8, 14 and 15 each depend either directly or indirectly from claim 1, and the Official Action acknowledges that the rejection of each claim depends in part on the rejection of claim 1 over Osario. However, as discussed above, the Osario reference fails to disclose several features recited in claim 1. Further, none of the secondary references remedy these deficiencies. Therefore, as none of the prior art references, either standing alone or when taken in combination, disclose or suggest

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every element of the claimed invention, Applicants respectfully submit that a proper §103(a) rejection according to the guidelines set forth in MPEP §2143 has not been established and should therefore be withdrawn.

Further, with respect to the Hochschuler reference and the rejection of claim 2, Applicants respectfully submit that this reference does not disclose removal of the container from the bone cavity. Rather, Figures 25-27 show that exact opposite, that is, how to leave the container in the bone cavity permanently. The container at the right is filled with cement through the fill needle 84 and then the needle is removed. A point of weakness 83 in the fill tube allows the fill tube to be broken off, thus leaving the container permanently implanted in the bone cavity. This is clearly contrary to the presently claimed method, wherein step g) recites that the pocket is separated from the hardened cement. Accordingly, Applicants respectfully submit that even if Osario did not have the deficiencies described in detail above, the combination of references would still fail to disclose or suggest every element of the claimed invention and therefore could not properly support a §103(a) rejection according to the guidelines set forth in MPEP §2143.

Finally, Applicants note paragraph [0009] of the Hochschuler references, which discloses that the container may be porous to the bone filler material. Applicants note that this is clearly different from the claimed invention, since the claimed invention is directed to a pocket made of a material that is porous to the liquid component of the cement paste, but not the solid. The container described in the reference would allow both components of the cement paste to escape the container and therefore the powder to liquid ratio would remain unchanged. The present invention claims a material that retains the powder component of the cement paste and that calls for the cement past to harden within the pocket, not outside of the pocket as would happen in Hochschuler if the cement were allowed to flow through and out of the container. These differences further distinguish the prior art from the instant application and support the patentability of the presently amended claims.

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In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,
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